CERTIFICATE OF MAILING

Deposited: 12/01/2003

thereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated above.

Susan Strickland

Attorney Docket No.: 00711CIP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Pal et al.

Group:

Unassigned

Serial No.:

10/612,192

Examiner:

Unassigned

Filed:

July 2, 2003

Customer No.:

35467

For:

HIV IMMUNOGENIC COMPLEXES

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

SIR:

In order to fulfill the requirements of candor and good faith set forth in 37 C.F.R. § 1.56, Applicants submit this Information Disclosure Statement in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98.

FOREIGN PATENT REFERENCES

Patent No.:

Publication Date:

Country:

EP 0385909

09/05/1990

European Convention

WO 9205799

04/16/1992

PCT

NON-PATENT REFERENCES

- 1. Allan, J.S. et al., "Major Glycoprotein Antigens That Induce Antibodies in AIDS Patients are Encoded by HTLV-III", Science, 228:1091-1094 (1985).
- 2. Celada, F. et al., "Antibody Raised Against Soluble CD-4rgp 120 Complex Recognizes the CD4 Moiety and Blocks Membrane Fusion Without Inhibiting CD4-gp120 Binding", J. Exp. Med., 172:1443-1150 (1990).
- 3. Chamov, S.M. et al., "Conjugation of Soluble CD4 without Loss of Biological Activity via a Novel Carbohydrate Directed Cross-Linking Reagent", Journal of Biological Chemistry, 267 (22): 15916-15922 (1992).
- 4. Chanh, T.C. et al., "Induction of Anti-HIV Neutralizing Antibodies by Synthetic Peptides", EMBO J, 5:3065-3071 (1986).
- 5. Cohen, J., "Jitters Jeopardizing Aids Vaccine Trials", Science, 262:980-981 (1993).
- 6. Dalgleish, A.G. et al., "The CD4 (T4) Antigen is an Essential Component of the Receptor for the AIDS Retrovirus:, Nature, 312:763-767, 1984.
- 7. Dolin et al., "The Safety and Innumogenicity of Human Immunodeficiency Virus Type 1 (HIV-1) Recombinant gp160 Candidate Vaccine in Humans", Ann Intern Med, 114:119-27 (1991).
- 8. Dowd, C.S. et al., "β-Turn Phe in HIV-1 Env Binding Site of CD4 and CD4 Mimetic Miniprotein Enhances ENV Binding Affinity But Is Not Required for Activation of Co-Receptor/17b Site.
- 9. Edelman et al., International Review of Immunology, 7:151-66 (1990).
- 10. Ezekowitz, R.A. et al., "A Human Serum Mannose-Binding Protein Inhibits In Vitro Infection by the Human Immunodeficiency Virus", J. Exp. Med., 169:185-196 (1989).
- 11. Gattegno, L. et al., "Lectin-Carbohydrate Interactions and Infectivity of Human Immunodeficiency Virus Type 1 (HIV-1)", AIDS Res. Hum. Retroviruses, 8:27-37 (1992).
- 12. Gershoni, J.M. et al., "HIV Binding to its Receptor Creates Specific Epitopes for the

- CD4/gp120 Complex", FASEB Journal, 7:12, 1185-1187 (Sept. 1993).
- 13. Geyer, H. et al., "Carbohydrates of Human Immunodeficiency Virus Structures of Oligosaccharides Linked to the Envelope Glycoprotein 120", J. Biol. Chem., 263:11760—11767 (1988).
- 14. Grewe, C. et al., "HIV: Early Virus-Cell Interactions", J. Acq. Immune Def. Synd., 3:965-974 (1990).
- 15. Harlow et al., "Antibodies, A Laboratory Manual", Cold Spring Harbor Laboratory, (1988).
- 16. Hart, T.K. et al., "Binding of Soluble CD4 Proteins to Human Immunodeficiency Virus Type 1 and Infected Cells Induces Release of Envelope Glycoprotein gp120", Proc. Natl. Acad. Sci. USA, 88:2189-2193 (1991).
- 17. Haynes, B.F. et al., "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development", Science, 260:1279-1286, (May 1993).
- 18. Ho, D.D. et al., "Conformational Epitope on gp120 important in CD4 Binding and Human Immunodeficiency Virus Type 1 Neutralization Identified by a Human Monoclonal Antibody", J. Virol., 65:489-493 (1991).
- 19. Ho, D.D. et al., "Second Conserved Domain of gp120 is Important for HIV Infectivity and Antibody Neutralization", Science, 239:1021-1023 (1988).
- 20. Kahn, J.O. et al., "The Safety and Pharmacokinetics of Recombinant Soluble CD4 (rCD4) in Subjects with the Acquired Immunodeficiency Syndrom (AIDS) and AIDS-Related Complex", A Phase 1 Study-Ann. Inter. Med., 112:254-261 (1990).
- 21. Kang, C. et al., FASEB Journal, 8:5: Abstract 5567 (April 1994).
- 22. Larkin, M. et al., "Oligosaccharide-Mediated Interactions of the Envelope Glycoprotein gp120 of HIV-1 that are Independent of CD4 Recognition", AIDS, 3:793-798 (1989).
- 23. Masuda, T. et al., "Generation of Neutralization-Resistant HIV-1 In Vitro Due to Amino Acid Interchanges of Third Hypervariable env. Region", J. Immunol., 145:3240-3246 (1990).
- 24. McDougal, J.S et al., "Binding of HTLV-II/LAV to T4+T Cells By a Complex of the 110K Viral Protein and the T4 Molecule", Science, 231:382-385 (1986).

- 25. Mizuochi, T. et al., "Diversity of Oligosaccharide Structures on the Envelope Glycoprotein gp120 of Human Immunodeficiency Virus I from the Lympoblastoid Cell Line H9, Presence of Complex-Type Oligosaccharides with Bisecting Nacetylglucosamine Residues", J. Biol. Chem., 265:1139-1142 (1990).
- 26. Moore, J. P. et al., "Dissociation of gp120 from HIV-1 Virions Induced Soluble CD4", Science, 250:1139-1142 (1990).
- 27. Ohno, T. et al., "A Broadly Neutralizing Monoclonal Antibody that Recognizes that V3 Region of Human Immunodeficiency Virus Type 1 Glycoprotein gp120", Proc. Natl. Acad. Sci. USA, 88:10726-10729, (1991).
- 28. Pal, R. et al., "Characterization of a Neutralizing Monoclonal Antibody to the External Glycoprotein of HIV-1", Intervirology, in Press.
- 29. Pal, R. et al., "Conformational Perturbation of the Envelope Glycoprotein gp120 of Human Immunodeficiency Virus Type 1 by Soluble CD4 and the Lection Succinyl Con A", Virology, 194:833-837 (1993).
 - 30. Putney, S., "How Antibodies Block HIV Infection: Pathes to an AIDS Vaccine", TIBS, 17:191-196 (1992).
- 31. Putney, S. et al., "Structural and Functional Features of the HIV Envelope Glycoprotein and Considerations for Vaccine Development", Biotechnology, 14:81-110 (1990).
- 32. Robert-Guroff, M., "HIV-Neutralizing Antibodies: Epitope Identification and Significance for Future Vaccine", Int. Rev. Immunology, 7:15-30 (1990).
- 33. Robey, W.G. et al., "Prospect for Prevention of Human Immunodeficiency Virus Infection: Purified 120-kDA Envelope Glycoprotein Induces Neutralizing Antibody", Proc. Natl. Acad. Sci. USA, 83:7023-7027 (Sept. 1986).
- 34. Robinson, W.E. Jr. et al., "Evidence That Mannos yl Residues are Involved in Human Immunodeficiency Virus Type I (HIV-1) Pathogenesis" AIDS Res. Hum. Retroviruses, 3:265-282 (1987).
- 35. Sattentau, Q.J. et al., "Conformational Changes Induced in the Human Immunodeficiency Virus Envelope Glycoprotein by Soluble CD4 Binding", J. Exp. Med., 174:407-415 (Aug. 1991).
- 36. Schooley, R.T. et al., "Recombinant Soluble CD4 Therapy in Patients with the

- Acquired Immunodeficiency Syndrome (AIDS) and AIDS- Related Complex A Phase I-II Escalating Dosage Trial", Ann. Int. Med., 112:247-253 (1990).
- 37. Sun, N.C. et al., "Generation and Characterization of Monoclonal Antibodies to the Putative CD4-Binding Domain of Human Immunodeficiency Virus Type I gp120 Envelope Glycoprotein", J. Virology, 63:3579-3585 (1992).
- 38. Thali, M. et al., "Discontinuous Conserved Neutralization of Epitopes Overlapping the CD4 Binding Region of Human Immunodeficiency Virus Type 1 gp120 Envelope Glycoprotein", J. Virology, 66:5636-5641 (1992).
- 39. Veronese, F.D. et al., "Characterization of gp41 as the Transmembrane Protein Coded by the HTLV-III/LAV Envelope Gene", Science, 229:1402-1405, (1985).
- 40. Veronese, F.D. et al., "Delineation of Immunoreactive Conserved Regions in the External Glycoprotein of the Human Immunodeficiency Virus Type 1", AIDS Res. Human Retroviruses, 8:1125-1132, (1992).
- 41. Watanabe, M. et al., "Chimpanzees Immunized with Recombinant Soluble CD4 Develop Anti-Self CD4 Antibody Responses with Anti-Human Immunodeficiency Virus Activity", Proc. Natl. Acad. Sci. USA, 89:5103-5107 (1992).
- 42. Watanabe, M. et al., "Soluble Human CD4 Elicits an Antibody Response in Rhesus Monkeys that Inhibits Simian Immunodeficiency Virus Replication", Proc. Natl. Acad. Sci. USA, 88:120-124 (1991).

Copies of the above-listed references with the exception of non-patent reference numbers 9, 15, 28, 30, 31, 32, and 35 are enclosed herewith. Applicants will submit these non-patent references in a Supplemental Information Disclosure Statement once they are obtained.

The above-listed references are also listed in Form PTO-1449 which is also enclosed herewith.

This submission is not an admission that the information disclosed in the references is material to the patentability of the invention disclosed and/or claimed in the above-identified application. Accordingly, Applicants respectfully submit that the application is in all respects in

condition for examination on the merits.

The Commissioner is hereby authorized to charge any fees in connection herewith to Deposit Account No. 50-0364.

Respectfully submitted)

Samir R. Patel - Reg. No. 44,998

Patent Counsel

bioMérieux, Inc. Patent Department 100 Rodolphe Street Durham, NC 27712 Tel. No. (919) 620-2914

Enclosures: PTO-1449 w/37 references

DEC 0 3 2003

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) U.S. PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO.	SER. NO.	
00711 CIP	10/612,192	
Applicant: PAL et al.		
FILING DATE	GROUP	
July 2, 2003	Unassigned	

(37 CFR 1.98(b))

U.S. PATENT DOCUMENTS

Examiner Initial	Cite No. ¹	Patent Number	Issue Date	Patentee	Class/ Subclass	Filing Date
			1			
						
]			
			1		1	1

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATIONS

Examiner Initial	Document Number	Publication Date	Country or Patent Office	Class/ Subclass	Translation Yes/No
	EP 0385909	09/05/1990	European Convention		
	WO 9205799	04/16/1992	PCT		
	İ				
<u> </u>					
l ——					

OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

Examiner Initial	Cite No. ¹	
		Allan, J.S. et al., "Major Glycoprotein Antigens That Induce Antibodies in AIDS Patients are Encoded by HTLV-III", Science, 228:1091-1094 (1985).
		Celada, F. et al., "Antibody Raised Against Soluble CD-4rgp 120 Complex Recognizes the CD4 Moiety and Blocks Membrane Fusion Without Inhibiting CD4-gp120 Binding", J. Exp. Med., 172:1443-1150 (1990).
		Chamov, S.M. et al., "Conjugation of Soluble CD4 without Loss of Biological Activity via a Novel Carbohydrate Directed Cross-Linking Reagent", Journal of Biological Chemistry, 267 (22): 15916-15922

324	(1992).
2003 EMARKS	Chanh, T.C. et al., "Induction of Anti-HIV Neutralizing Antibodies by Synthetic Peptides", EMBO J, 5:3065-3071 (1986).
	Cohen, J., "Jitters Jeopardizing Aids Vaccine Trials", Science, 262:980-981 (1993).
	Dalgleish, A.G. et al., "The CD4 (T4) Antigen is an Essential Component of the Receptor for the AIDS Retrovirus:, Nature, 312:763-767, 1984.
	Dolin et al., "The Safety and Innumogenicity of Human Immunodeficiency Virus Type 1 (HIV-1) Recombinant gp160 Candidate Vaccine in Humans", Ann Intern Med, 114:119-27 (1991).
	Dowd, C.S. et al., "β-Turn Phe in HIV-1 Env Binding Site of CD4 and CD4 Mimetic Miniprotein Enhances ENV Binding Affinity But Is Not Required for Activation of Co-Receptor/17b Site
	Edelman et al., International Review of Immunology, 7:151-66 (1990).
	Ezekowitz, R.A. et al., "A Human Serum Mannose-Binding Protein Inhibits In Vitro Infection by the Human Immunodeficiency Virus", J. Exp. Med., 169:185-196 (1989).
	Gattegno, L. et al., "Lectin-Carbohydrate Interactions and Infectivity of Human Immunodeficiency Virus Type 1 (HIV-1)", AIDS Res. Hum. Retroviruses, 8:27-37 (1992).
	Gershoni, J.M. et al., "HIV Binding to its Receptor Creates Specific Epitopes for the CD4/gp120 Complex", FASEB Journal, 7:12, 1185-1187 (Sept. 1993).
	Geyer, H. et al., "Carbohydrates of Human Immunodeficiency Virus Structures of Oligosaccharides Linked to the Envelope Glycoprotein 120", J. Biol. Chem., 263:11760—11767 (1988).
	Grewe, C. et al., "HIV: Early Virus-Cell Interactions", J. Acq. Immune Def. Synd., 3:965-974 (1990).
	Harlow et al., "Antibodies, A Laboratory Manual", Cold Spring Harbor Laboratory, (1988).
	Hart, T.K. et al., "Binding of Soluble CD4 Proteins to Human Immunodeficiency Virus Type 1 and Infected Cells Induces Release of Envelope Glycoprotein gp120", Proc. Natl. Acad. Sci. USA, 88:2189-2193 (1991).
	Haynes, B.F. et al., "Scientific and Social Issues of Human Immunodeficiency Virus Vaccine Development", Science, 260:1279-1286, (May 1993).
	Ho, D.D. et al., "Conformational Epitope on gp120 important in CD4 Binding and Human Immunodeficiency Virus Type 1 Neutralization

10115	
DEC 0 3 5003	FICE C
TRADEMAN	

<i>⊊</i> /	
<u>ē</u>	Identified by a Human Monoclonal Antibody", J. Virol., 65:489-493 (1991).
	Ho, D.D. et al., "Second Conserved Domain of gp120 is Important for HIV Infectivity and Antibody Neutralization", Science, 239:1021-1023 (1988).
	Kahn, J.O. et al., "The Safety and Pharmacokinetics of Recombinant Soluble CD4 (rCD4) in Subjects with the Acquired Immunodeficiency Syndrom (AIDS) and AIDS-Related Complex", A Phase 1 Study-Ann. Inter. Med., 112:254-261 (1990).
	Kang, C. et al., FASEB Journal, 8:5:Abstract 5567 (April 1994).
	Larkin, M. et al., "Oligosaccharide-Mediated Interactions of the Envelope Glycoprotein gp120 of HIV-1 that are Independent of CD4 Recognition", AIDS, 3:793-798 (1989).
	Masuda, T. et al., "Generation of Neutralization-Resistant HIV-1 In Vitro Due to Amino Acid Interchanges of Third Hypervariable env. Region", J. Immunol., 145:3240-3246 (1990).
	McDougal, J.S et al., "Binding of HTLV-II/LAV to T4+T Cells By a Complex of the 110K Viral Protein and the T4 Molecule", Science, 231:382-385 (1986).
	Mizuochi, T. et al., "Diversity of Oligosaccharide Structures on the Envelope Glycoprotein gp120 of Human Immunodeficiency Virus I from the Lympoblastoid Cell Line H9, Presence of Complex-Type Oligosaccharides with Bisecting N-acetylglucosamine Residues", J. Biol. Chem., 265:1139-1142 (1990).
	Moore, J. P. et al., "Dissociation of gp120 from HIV-1 Virions Induced Soluble CD4", Science, 250:1139-1142 (1990).
	Ohno, T. et al., "A Broadly Neutralizing Monoclonal Antibody that Recognizes that V3 Region of Human Immunodeficiency Virus Type 1 Glycoprotein gp120", Proc. Natl. Acad. Sci. USA, 88:10726-10729, (1991).
	Pal, R. et al., "Characterization of a Neutralizing Monoclonal Antibody to the External Glycoprotein of HIV-1", Intervirology, in Press.
	Pal, R. et al., "Conformational Perturbation of the Envelope Glycoprotein gp120 of Human Immunodeficiency Virus Type 1 by Soluble CD4 and the Lection Succinyl Con A", Virology, 194:833-837 (1993).
	Putney, S., "How Antibodies Block HIV Infection: Pathes to an AIDS Vaccine", TIBS, 17:191-196 (1992).
	Putney, S. et al., "Structural and Functional Features of the HIV Envelope Glycoprotein and Considerations for Vaccine Development", Biotechnology, 14:81-110 (1990).

DEC 0

E vc	
2003 30 10 10 10 10 10 10 10 10 10 10 10 10 10	Robert-Guroff, M., "HIV-Neutralizing Antibodies: Epitope Identification and Significance for Future Vaccine", Int. Rev. Immunology, 7:15-30 (1990).
	Robey, W.G. et al., "Prospect for Prevention of Human Immunodeficiency Virus Infection: Purified 120-kDA Envelope Glycoprotein Induces Neutralizing Antibody", Proc. Natl. Acad. Sci. USA, 83:7023-7027 (Sept. 1986).
	Robinson, W.E. Jr. et al., "Evidence That Mannos yl Residues are Involved in Human Immunodeficiency Virus Type I (HIV-1) Pathogenesis" AIDS Res. Hum. Retroviruses, 3:265-282 (1987).
	Sattentau, Q.J. et al., "Conformational Changes Induced in the Human Immunodeficiency Virus Envelope Glycoprotein by Soluble CD4 Binding", J. Exp. Med., 174:407-415 (Aug. 1991).
	Schooley, R.T. et al., "Recombinant Soluble CD4 Therapy in Patients with the Acquired Immunodeficiency Syndrome (AIDS) and AIDS-Related Complex A Phase I-II Escalating Dosage Trial", Ann. Int. Med., 112:247-253 (1990).
	Sun, N.C. et al., "Generation and Characterization of Monoclonal Antibodies to the Putative CD4-Binding Domain of Human Immunodeficiency Virus Type I gp120 Envelope Glycoprotein", J. Virology, 63:3579-3585 (1992).
	Thali, M. et al., "Discontinuous Conserved Neutralization of Epitopes Overlapping the CD4 Binding Region of Human Immunodeficiency Virus Type 1 gp120 Envelope Glycoprotein", J. Virology, 66:5636-5641 (1992).
	Veronese, F.D. et al., "Characterization of gp41 as the Transmembrane Protein Coded by the HTLV-III/LAV Envelope Gene", Science, 229:1402-1405, (1985).
	Veronese, F.D. et al., "Delineation of Immunoreactive Conserved Regions in the External Glycoprotein of the Human Immunodeficiency Virus Type 1", AIDS Res. Human Retroviruses, 8:1125-1132, (1992).
	Watanabe, M. et al., "Chimpanzees Immunized with Recombinant Soluble CD4 Develop Anti-Self CD4 Antibody Responses with Anti-Human Immunodeficiency Virus Activity", Proc. Natl. Acad. Sci. USA, 89:5103-5107 (1992).
	Watanabe, M. et al., "Soluble Human CD4 Elicits an Antibody Response in Rhesus Monkeys that Inhibits Simian Immunodeficiency Virus Replication", Proc. Natl. Acad. Sci. USA, 88:120-124 (1991).

Sheet 5 of 5

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.